

### Remarks

Claims 1-17 are pending. Claims 1-17 are rejected. No claim has been canceled. Claims 1, 3, 5, 7, 8, 10, 12 and 15 have been amended. No new matter has been added. Importantly, the claim amendments should not be construed to be an acquiescence to any of the claim rejections. Rather, the amendments to the claims are being made solely to expedite the prosecution of the above-identified application. The Applicants expressly reserve the right to further prosecute the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application. 35 USC § 120.

### Response to Claim Rejections Based on 35 USC § 112¶1

Claims 1-6, 8 and 12-17 are rejected for lacking enablement. Specifically, the Examiner contends that for one skilled in the art to “prepare another gel or network that has the characteristics of that when copolymerizing the monomer of claim 7 with N-isopropylacrylamide would [...] require an undue amount of further experimentation.” The Applicants respectfully traverse.

Firstly, the Applicants respectfully submit that one of ordinary skill in the art would be able to produce and identify compounds of the instant invention through the use of standard techniques. Guidance as to how to perform such techniques is provided in the Exemplification section of the specification and summarized herein. For example, in Example 1 (pages 23-24 of the specification) the Applicants have disclosed the details of a method for synthesizing imprinters. In addition, in Example 2 (page 24) the Applicants have disclosed the preparation of gels. The Examiner is also directed to pages 14-18 of the specification for a discussion of the preferred components to be used in the present invention.

Secondly, the Applicants would respectfully emphasize the distinction between experimentation and *undue* experimentation. It is only undue experimentation that may form the basis of an enablement rejection under 35 U.S.C. § 112¶1. For example, in *In re Strahilevitz*, 668 F. 2d 1229, 212 U.S.P.Q. 561 (C.C.P.A. 1982), wherein those Applicants sought to claim broadly a method and devices for removing haptens, antigens, and antibodies from blood. Notably, the Applicants in *In re Strahilevitz* had described the invention with specificity, but had not disclosed even a single operative embodiment. The Court acknowledged that the claims at

issue were extremely broad. *Nevertheless, the Court reversed the Board's holding of nonenablement, pointing out that 35 USC § 112 does not require working examples.* In fact, the Court found the broad claims enabled throughout their scope.

As the decision in *Strahilevitz* illustrates, the requirements of 35 USC § 112 do not necessarily limit an Applicant's claim scope to those embodiments actually disclosed in the specification. The *Wands*' court (See *In re Wands*, 858 F. 2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988), synthesizing precedent, crystallized a list of eight factors by which an Examiner or reviewing court can assess whether a disclosure is sufficient to enable one of ordinary skill in the art to practice a claimed invention throughout its scope without having to engage in undue experimentation: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of a working example; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. The *Wands* factors form a web of interacting and overlapping indices of disclosure sufficiency. For example, "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *Wands*, 8 U.S.P.Q. 2d at 1404 (quoting *Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (Bd. App. 1982)).

Importantly, the Applicants respectfully submit that synthesizing simple monomers and polymerizing them is routine experimentation to one of ordinary skill in the art. Further, the Applicants respectfully assert that sufficient guidance with respect to the direction in which the experimentation should proceed has been supplied in the Exemplification section of the instant application. Moreover, the level of ordinary skill in the art of polymer chemistry is a Ph.D. in chemistry or polymer science.

Therefore, the Applicants respectfully contend that the rejected claims comply with the requirements 35 U.S.C. § 112 ¶1.

**Response to Claim Rejections Based on 35 USC § 112 ¶2**

Claims 1-17 are rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner cites a number of such issues and they are traversed, in the order in which they were made, below.

The Examiner suggests the introduction of the word “molecular” before the word “imprinter” in claim 1. Solely in order to expedite the prosecution of this application, claim 1 has been thus amended.

The Examiner objects to the term “functional group” as being relative and subjective. The Applicants’ intent was that the words “functional group” would be given their customary meaning in the art of organic chemistry, e.g., as found in the *American Heritage® Dictionary of the English Language, Fourth Edition* (© 2000 Houghton Mifflin Company). This dictionary defines “functional group” as “an atom or group of atoms, such as a carboxyl group, that replaces hydrogen in an organic compound and that defines the structure of a family of compounds and determines the properties of the family.”

The Examiner contends that claim 1 is unclear for it requires breaking a covalent bond in the tether without requiring the tether to contain a breakable covalent bond. Solely in order to expedite the prosecution of the application, claim 1 has been amended to require explicitly that the tether contain a breakable covalent bond. Dependent claims 3, 5, 8 and 10 have been also amended to conform to the amendment to claim 1.

As the Examiner contends that the recitation of “without using a template” in the preamble of claims 5, 8 and 10, is confusing, the Applicants have amended said claims to remove “without using a template.”

The Examiner objects to claims 7 and 8 as being unclear by requiring the polymer of claim 5, wherein claim 5 is drawn to a method. The preamble of claim 7 should read the “method of claim 5” not the “monomer of claim 5.” Support for the Applicants’ intent for claim 7 to be a method claim can be found in claim 9, which reads the “method of claim 7.” The Applicants apologize for this typographical error and have amended claim 7 to correct it. Claim 8 also contained a typographical error. This claim intended to reference the monomer described in claim 4, not claim 5 (which is a method claim). Support for the Applicants intention can be found in examples 1 and 2 of the exemplification, wherein such a method is performed.

The Examiner objects to claim 9, a method claim, being dependent on claim 7, which was erroneously presented as a compound claim. As noted above, this has been corrected.

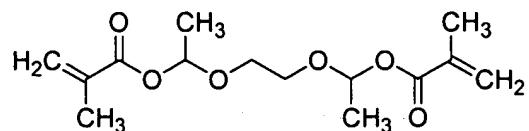
The Examiner contends that claims 12-17 are unclear for lacking structural and functional information regarding “separation materials” and “sensors.” Firstly, these claims are product-by-process claims. As such, the Applicants believe structural and functional information is not required because the products claimed are defined by the methods (*e.g.*, claims 2, 8 and 10) used to produce them. With respect to claims 12 and 15, since claim 2 refers to the method of claim 1, these claims have been amended to refer directly to the method of claim 1.

Therefore, based on the explanations and amendments presented above, the Applicants respectfully request the withdrawal of these rejections based on 35 USC § 112¶2.

#### **Response to Claim Rejections Based on 35 USC § 102(b) and 102(e)**

Claims 1-5, 8, 12, 13, 15 and 16 are rejected as being anticipated by two references: Ruckenstein et al. (AF in PTO-1449) and Ruckenstein et al. (US Patent No. 6,323,360). The Examiner contends that these references disclose “a breakable cross-linker (Figure 1) that is ethylene glycol di(1-methacryloyloxy)ethyl ether [which has] two polymerizable double bonds, two functional groups and a covalent bond breakable by hydrolysis linking the functional groups.” The Applicants respectfully traverse.

The Ruckenstein references disclose the following compound:



However, contrary to the Examiner’s contention, this compound does not fall within the scope of the claimed molecular imprinter. Importantly, the specification of the instant application indicates that a molecular imprinter of claim 1 must comprise a tether containing a breakable covalent bond.

In case of the functional crosslinkers containing a 1,2-glycol structure, the materials after polymerization are treated with an oxidizing agent such as sodium periodate. Resulting materials are preferably treated with a reducing agent such as sodium borohydride in order to convert aldehyde group to more stable hydroxyl group. Resulting materials are preferably washed and purified with

water. In case of the compounds where the breakable bond is disulfide link, the materials after polymerization are treated with a reducing agent such as sodium borohydride. Resulting materials are treated with a oxidizing agent such as hydrogen peroxide in order to convert thiol group to sulfonium group. *Specification*, page 18 (section entitled “Breaking the breakable bond”).

As the foregoing excerpt from the instant application makes clear, hydrolysis, e.g., of an acetal, does not fall within the scope of “breaking a breakable covalent bond” in the Applicants’ claims. Therefore, with respect to the compound taught by Ruckenstein et al. the tether that connects the two methacrylates does not contain a breakable covalent bond. Hydrolysis to remove the tether after polymerization is not the same as breaking a covalent bond within the tether. Accordingly, the Applicant respectfully requests the withdrawal of the rejections based on 35 USC § 102(b) and 102(e).

**Response to Claim Rejections Based on 35 USC § 103(a)**

Claims 1-5, 8, 12, 13, 15 and 16 are rejected as being unpatentable over Lipskier (US 5,841,493), Domb (US 5,858,296), Singh et al. (US 6,248,842 B1), Mosbach et al. (US 6,316,235 B1) or Tanaka et al. (US 5,801,221) in view of the above-mentioned Ruckenstein references. None of the cited references includes a tether comprising a breakable covalent bond. Therefore, none of these references alone, or in combination, renders the instant invention unpatentable. The Applicants respectfully remind the Examiner that in order “to establish a *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” MPEP 2143.03. See also *In re Royka*, 490 F.2d 981. Therefore, the Applicant respectfully requests the withdrawal of the rejections based on 35 USC § 103(a).

**Allowable Claims**

The Applicants gratefully acknowledge the Examiner's indication that claims 6, 7, 9, 10, 11, 14 and 17 are free of the prior art.

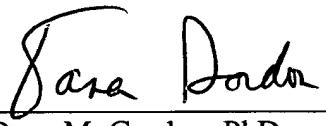
**Fees**

The Applicants believe there are no required fees in connection with the filing of this paper. Nevertheless, the Director is hereby authorized to charge any required fee to our Deposit Account, **06-1448**.

**Conclusion**

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

Respectfully submitted,  
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